REMARKS

FORMAL MATTERS

Applicants have amended claims 1, 14, 26, and 30. No new matter was added by way of these amendments.

Claims 1, 3, 9, 10, 14, and 26-30 are currently pending in this application.

ENABLEMENT REJECTION

The Examiner rejected claims 1, 3, 9, 10, 14, and 26-30 as not providing enablement for three key reasons. *See* Office Action at page 4. First, the Examiner states that the "instant disclosure does not enable a method of preventing a disease, e.g., septicemia." Office Action at page 4. Applicants respectfully traverse. Although Applicants believe that these concepts are supported by the specification, Applicants have deleted the term "preventing" from claims 1 and 26. Therefore, Applicants respectfully request that the Examiner withdraw this basis for rejection of the claims.

The Examiner also asserted that except for PTHrP, the instant disclosure fails to teach how to make and use antibodies that bind to other ligands of the PTHrP receptor. *See* Office Action at page 4. Applicants respectfully traverse. However, merely to expedite prosecution, Applicants have replaced the phrase "antibody that binds to a ligand of a PTHrP receptor to promote or inhibit binding between the ligand and the receptor" in claims 1 and 26 with "PTHrP antibody." Applicants reserve the right to pursue the other embodiments in a separate application. Applicants have also amended claims 14 and 30 to read "wherein the PTHrP antibody inhibits the binding of PTHrP to a PTH/PTHrP type I receptor." As the Examiner stated that "the specification

was enabling for a method of treating PTHrP-related septicemia with an anti-PTHrP antibody," Applicants request that the Examiner withdraw the enablement rejection.

Finally, the Examiner alleged that claims 1, 3, 9, 10, 14, and 26-30 are not enabled because "treatment of septicemia can apparently be achieved only by the action of an anti-PTHrP antibody through inhibition (or promotion) of binding between PTHrP and its receptor." Office Action at page 4. Applicants respectfully traverse. However, as described above, Applicants deleted these phrases from claims 1 and 26, rendering this basis of rejection moot. In light of these arguments and those outlined above, Applicants respectfully request that the Examiner withdraw the enablement rejection of claims 1, 3, 9, 10, 14, and 26-30.

WRITTEN DESCRIPTION REJECTION

The Examiner rejected claims 1, 3, 9, 10, 14, and 26-30 as lacking written description. Specifically, the Examiner alleges that, "the specification fails to provide sufficient description information, such as definitive structural features of the genus of 'ligand.'" Office Action at page 5. Applicants respectfully traverse. However, as described above, Applicants have replaced the phrase "ligand of a PTHrP receptor" in claims 1 and 26 with "PTHrP antibody." The specification provides sufficient written description of PTHrP antibodies, as the Examiner has agreed. *See* 5/18/04 Office Action at page 10. Applicants therefore assert that the claims, as amended, fulfill the written description requirement and request that the Examiner withdraw this rejection.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

The Examiner rejected claims 1, 3, 9, 10, 14, and 26-30 as being anticipated under 35 U.S.C. § 102(e) by Sato *et al.* (US2002/0165363 A1). *See* Office Action at page 5. Specifically, the Examiner asserts that "Sato et al. teach a method of administering to a patient (mice with cachexia) a same agent (a humanized PTHrP antibody or a human PTHrP antibody) as that of the instantly claimed method." Office Action at pages 5-6. Further, the Examiner alleges that "the intended uses and properties of a PTHrP antibody recited in the claims are inherent to the method taught by Sato et al." Office Action at page 6. Applicants respectfully traverse.

The M.P.E.P. provides that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P. § 2112, IV, citing *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Furthermore, Applicants respectfully note that inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed Cir. 1999) (emphasis added). There is nothing in the record that demonstrates that the cachexia subjects disclosed in Sato *et al.* were also suffering from septicemia. In fact, cachexia, which is a state of malnourishment, and septicemia, which is characterized by bacteria in the blood, are separate and distinct conditions. Therefore, the treatment of septicemia with a PTHrP antibody does not necessarily flow from the treatment of

cachexia with a PTHrP antibody. Again, there is no relationship or link between these diseases; therefore, inherency cannot be established.

Applicants also note that independent claims 1 and 26 have been amended to require that the PTHrP antibody is administered to "a patient in need of such treatment." Patients suffering from cachexia are not necessarily in need of treatment for septicemia. The unlikely and purely coincidental possibility that some patients may be suffering from both septicemia and cachexia and both conditions may be treated by administration of a PTHrP antibody does not legally suffice to show anticipation. Therefore, Applicants request that the Examiner withdraw this anticipation rejection of claims 1, 3, 9, 10, 14, and 26-30.

The Examiner also rejected claims 1, 3, 9, 10, 14, and 26-30 as being anticipated by Grunfeld *et al.* (WO 96/39184). Specifically, the Examiner alleges that Grunfeld *et al.* teach a method of treating septicemia with a humanized and human anti-PTHrP antibody. *See* Office Action at page 6. Applicants respectfully traverse.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P § 2131. In addition, the disclosure in an allegedly anticipating reference must provide an enabling disclosure of the desired subject matter. *See* M.P.E.P. § 2121.01. Contrary to the Examiner's assertion, Grunfeld *et al.* does not "clearly" disclose or teach the humanized or human antibodies that each are an element of the pending claims. The paragraph that the Examiner cites in support of the alleged disclosure refers to monoclonal antibodies, polyclonal antibodies, chimeric antibodies, and "other forms

chosen to make the antibodies most suitable for use in therapy." Office Action at page 6; *Grunfeld* at col. 3, lines 43-44. Additionally, Grunfeld *et al.* does not claim a humanized or human PTHrP antibody. Furthermore, the specification's reference to "other forms of antibodies" does not convey sufficient information so that a person skilled in the art is placed in possession of the claimed invention. In fact, the only antibodies taught by Grunfeld *et al.* are goat and rabbit antibodies. *See Grunfeld* at col. 5, lines 37-44. This, in combination with the marked absence of any teaching of humanized or human, must limit the teaching of Grunfled *et al.* to nonhuman antibodies, at best chimeric antibodies. In other words, Grunfeld *et al.* does not provide an enabling disclosure of humanized or human antibodies. Therefore, Applicants respectfully request that the Examiner withdraw the anticipation rejection of claims 1, 3, 9, 10, 14, and 26-30.

OBJECTION TO THE CLAIMS

The Examiner objected to claims 10 and 29 because the claims recite non-elected subject matter (species). *See* Office Action at page 7. Applicants will consider amending the claims to overcome this objection once patentable subject matter has been indicated in this case. Until then, Applicants request that the Examiner hold the objection in abeyance.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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